Exhibit A

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327 MDL 2327**
THIS DOCUMENT RELATES TO: *Wave 3 Cases*	**JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**

Intentional Oxidation of Prolene Mesh – Part 2

Supplemental Report of Dr. Shelby F. Thames

September 28, 2016

This report is a supplement to my August 8, 2016 report. It includes the completed FTIR characterization of intentionally oxidized Prolene. Plaintiff's experts have opined that the explant cleaning protocol (Figure 1) we developed, and use for examination of explanted samples in this litigation, in some way, 'destroys oxidation carbonyls' should they exist. To prove unequivocally this does not occur, an exemplar Prolene mesh (Gynecare TVT device 810041B) was intentionally oxidized via exposure to ultra violet light. This involved ultraviolet (UV) light exposure of pristine Prolene for 500 hours in a Q-Lab Q-Sun Xe-3 Xenon Test Chamber. Oxidation was affected according to an established and accepted testing protocol, i.e. ASTM G 155[1]. Following the ASTM G 155 protocol, chamber cyclic conditions were set to 4 hrs. "on", at 340 nm wavelength, 1.10 W/m^2 irradiation at 63°C, and 35% RH, using a daylight filter set, followed by 1 hr. off" (40°C and 35% RH).

Sample Name	1st Step	2nd Step	3rd Step	4th Step	5th Step	6th Step
Oxidized Prolene	Distilled water soak 1h	Desiccation drying 1 h, Analysis Before Cleaning	Distilled water. Water bath (80°C), 20h	NaOCl. Shaker, 30min	Distilled water. Rinse; soak 1h; Rinse	Desiccation drying 1 h, Analysis After Cleaning 1

Sample Name	7th Step	8th Step	9th Step	10th Step	11th Step	12th Step	13th Step	14th Step
Oxidized Prolene	Distilled water. Water bath (80°C), 20h	NaOCl. Ultrasonic bath, 1.5h	Distilled water. Rinse, ultrasonic bath 1h, rinse.	Desiccation drying 1 h, Analysis After Cleaning 2	Distilled water. Water bath (80°C), 20h	NaOCl. Ultrasonic bath, 4h	Distilled water. Rinse, ultrasonic bath 1h, rinse.	Desiccation drying 1 h, Analysis After Cleaning 3

Sample Name	15th Step	16th Step	17th Step	18th Step	19th Step	20th Step	21st Step	22nd Step	23rd Step
Oxidized Prolene	Distilled water. Water bath (80°C), 20h	0.8 mg/ml Proteinase K. Water bath (58°C), 20h	0.8 mg/ml Proteinase K. Ultrasonic bath, 2h	Distilled water. Rinse, ultrasonic bath 1h, rinse.	Desiccation drying 1 h, Analysis After Cleaning 4	Distilled water. Water bath (80°C), 20h	NaOCl. Ultrasonic bath, 4h.	Distilled water. Rinse, ultrasonic bath 1h, rinse.	Desiccation drying 1 h, Analysis After Cleaning 5

Figure 1. Explant Cleaning Protocol

A sample size of approximately 10 mm x 10 mm of the exemplar TVT device, lot 810041B, as noted in Figures 2 and 3, was placed in the UV exposure chamber (Figure 4).

Figure 2. Exemplar Gynecare TVT Device 810041B

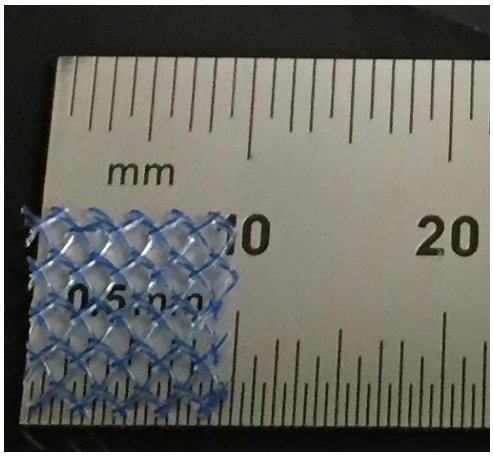

Figure 3. Exemplar TVT sample for UV exposure

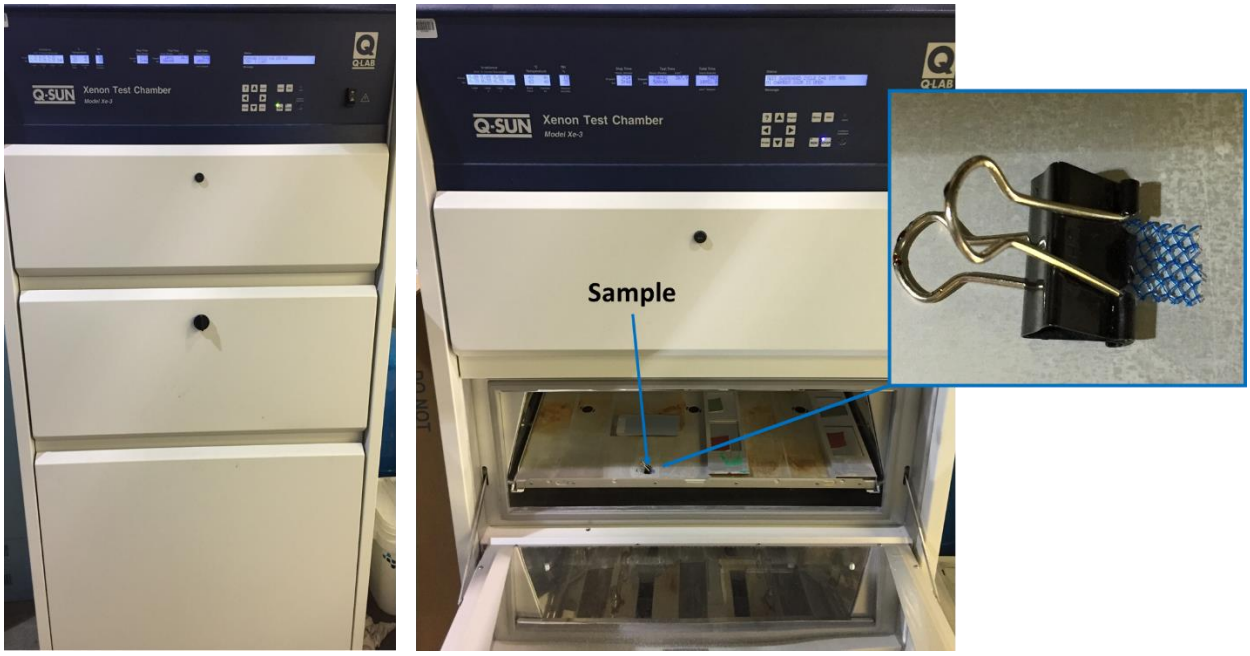

Figure 4. Q-Lab Q-Sun Xenon Test Chamber

The pristine TVT exemplar sample was characterized via Fourier Transform Infrared Microscopy (FTIR) with a Thermo-Nicolet Continuum FTIR Microscope (Figure 5) prior to UV exposure. The resulting spectrum (Figure 6) contains an inset image showing the penetrating IR beam location. The absorption frequency at 1742 cm^{-1}, indicative of Ethicon's DLTDP antioxidant, is also noted in my previous reports, which I rely upon, and is present in the spectrum.

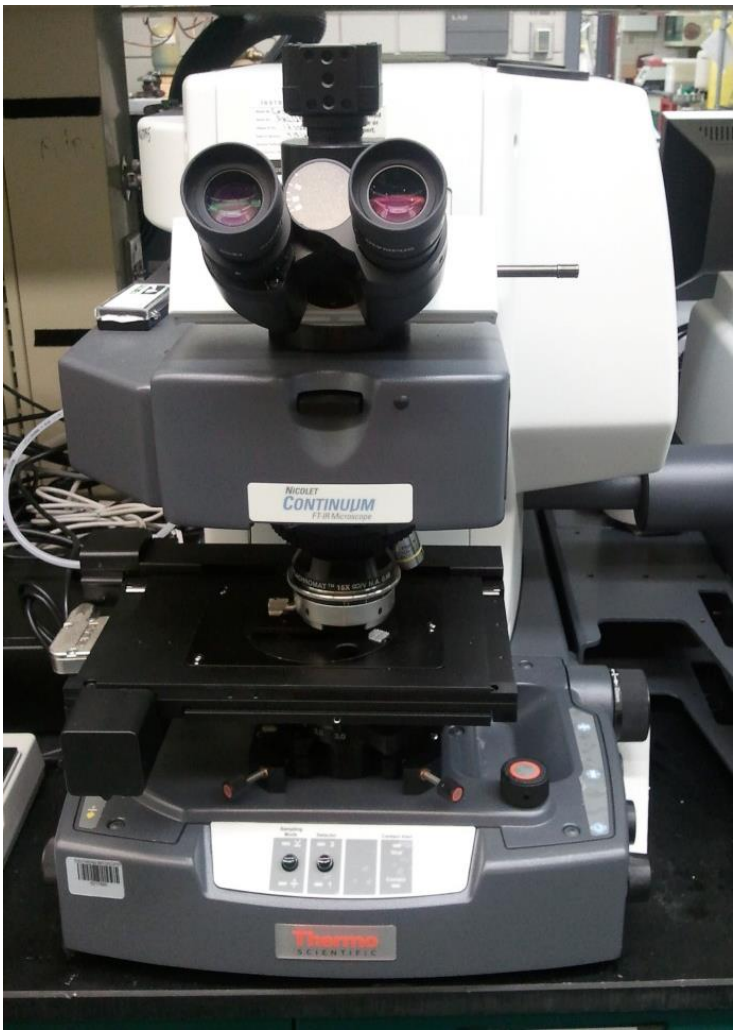

Figure 5. Thermo-Nicolet Continuum FTIR Microscope

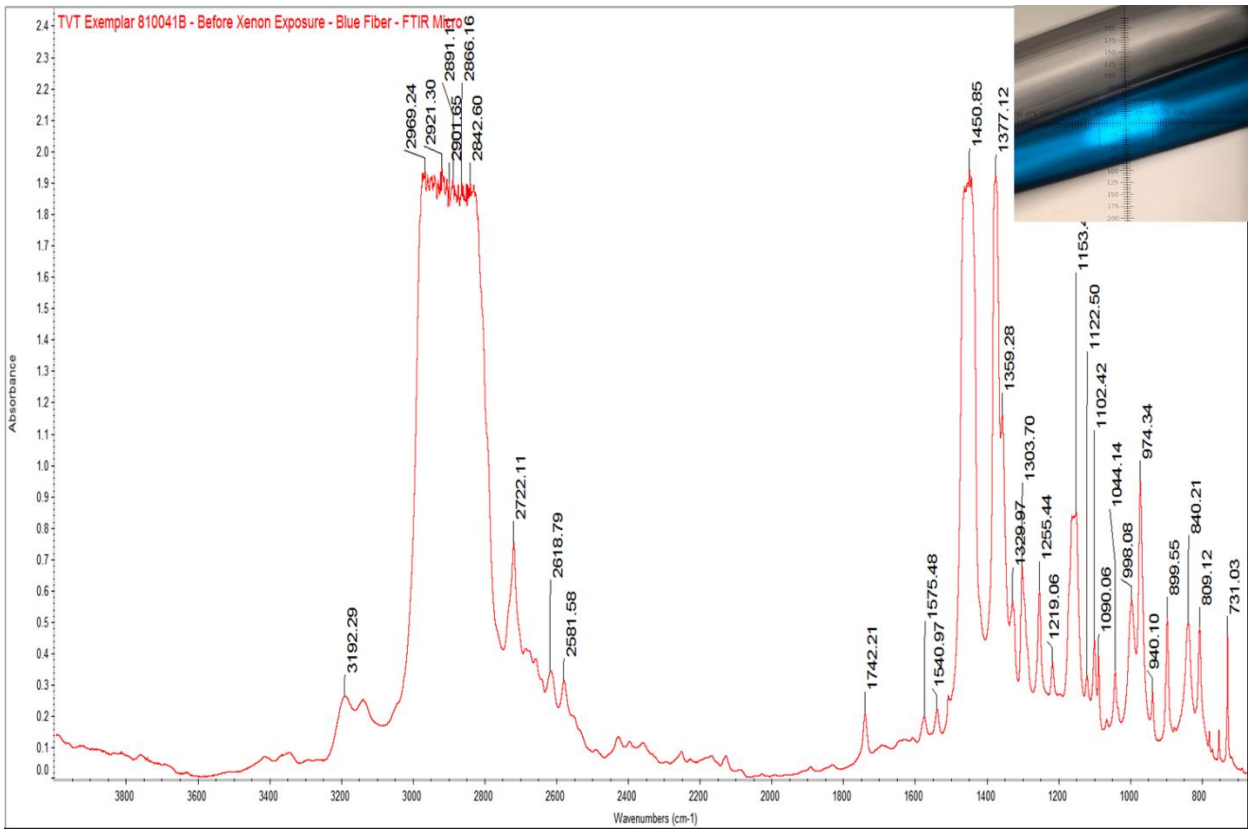

Figure 6. Pristine TVT Exemplar 810041B – Before Xenon Exposure – Blue Fiber

After 500 hrs. UV exposure the TVT exemplar was removed from the exposure chamber and again characterized via FTIR Microscopy (Figure 7). Oxidative degradation is evidenced by the presence of strong carbonyl absorption frequencies in the ~1740 cm^{-1} to 1713 cm^{-1} region accompanied by extensive fiber cracking.

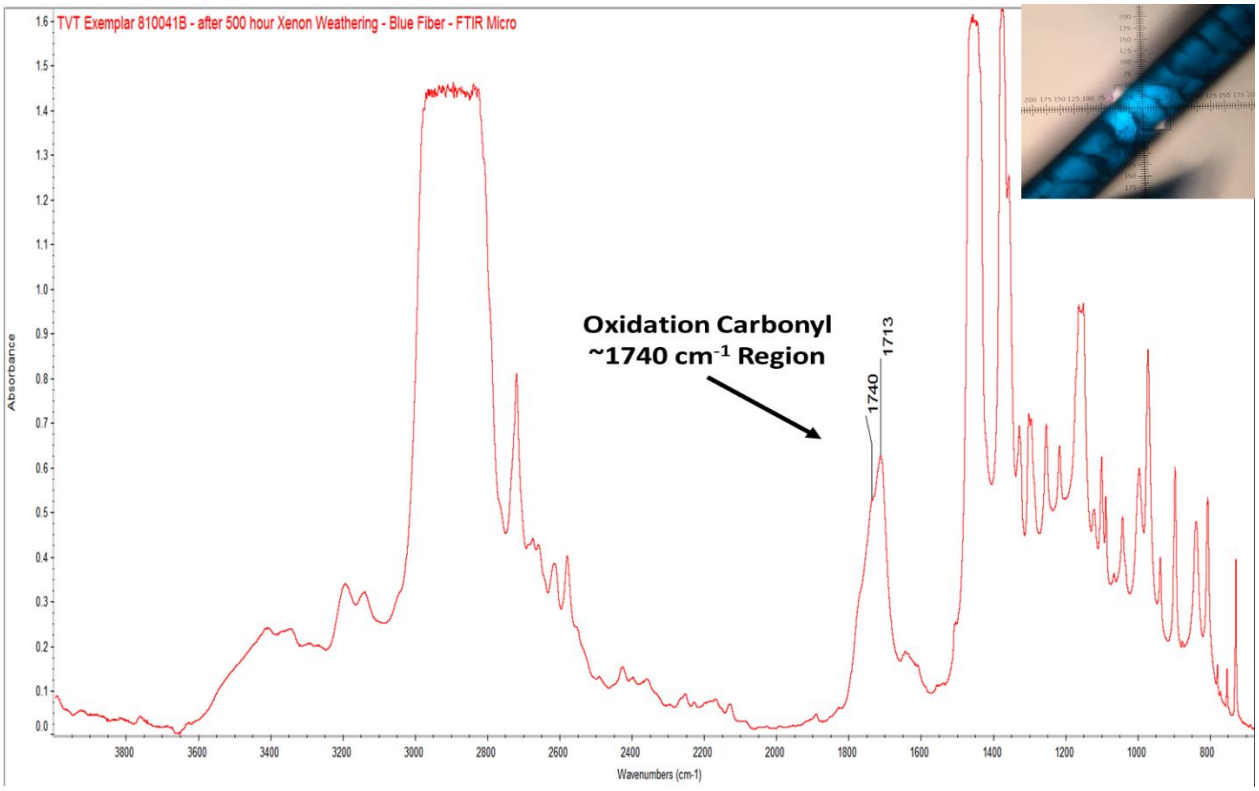

Figure 7. TVT Exemplar 810041B – After 500 hrs. Xenon Exposure – Blue Fiber

Plaintiffs have suggested the cleaning protocol (Fig. 1) removes carbonyl oxidation product(s) of Prolene should they exist. However, they have absolutely no supporting evidence supporting their claim. In order to verify this did not and does not happen, we have processed an intentionally oxidized Prolene exemplar through the cleaning protocol (Figure 1), with some modifications.

Consequently, the oxidized TVT exemplar (Figure 7) was immersed in 80°C water for 20 hours, removed, dried, and analyzed via FTIR microscopy (Figure 8 – red spectrum). The oxidized TVT exemplar was then immersed in sodium hypochlorite solution (NaOCl) on a shaker for 30 minutes, removed, dried, and again analyzed via FTIR microscopy (green spectrum). Although there was no flesh present to utilize sodium hypochlorite's oxidizing capacity, the FTIR spectral overlay demonstrates that carbonyl (oxidation) absorption did not diminish during, and as a result of, the cleaning protocol (Figure 8). The cleaning process (Fig. 1) was continued, utilizing the intentionally oxidized TVT exemplar, with FTIR analyses conducted after each cleaning stage (see Figures 8 and 13).

The FTIR spectra of Figure 13 unequivocally verifies that the cleaning protocol of Figure 1 does not remove oxidized carbonyl moieties from Prolene. Moreover, should oxidized Prolene be present it will be seen as a strong carbonyl frequency at or near ~1740 cm^{-1} (Figure 8)

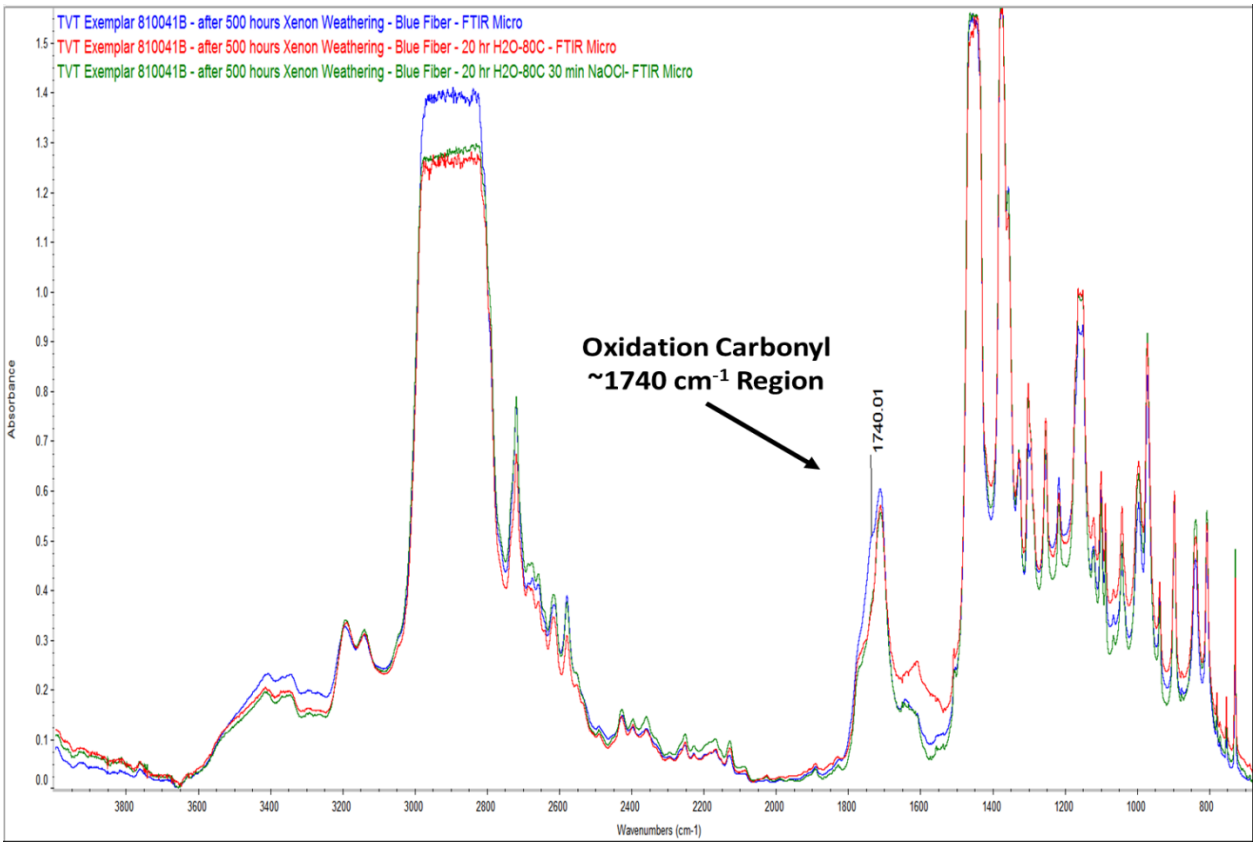

Figure 8. Overlay of Blue Fiber TVT Exemplar 810041B – After 500 hrs. Xenon Exposure (Blue Spectrum), After 20 hrs. Immersion in 80°C water (Red Spectrum), and After 30 min. Immersion in NaOCl (Green Spectrum)

Digital microscopy and scanning electron microscopy (SEM) of the before and after fiber exposure samples were conducted with a Keyence VHX-600 digital microscope (Figure 9) and a Zeiss Sigma VP FEG-SEM (Figure 10). One can readily observe oxidation effects upon Prolene as demonstrated by light microscopy and SEM fiber images (Figures 11 and 12, respectfully); before and after UV exposure. As a result of UV exposure, as described herein, Prolene fibers were grossly embrittled and demonstrated deep cracks resulting in fiber rupture via crack propagation.

In summary, our prior reports and current experimental results prove Prolene does not degrade (oxidize) *in vivo*. Furthermore, the experimental results reported herein of the purposeful oxidation of Prolene are yet more proof that:

- Prolene does not oxidize *in vivo*, and
- The cleaning protocol (Figure 1) utilized will not remove oxidized Prolene should it exist on an explant.

We have examined and tested approximately 50 explants, none of which have shown any indication of oxidation by FTIR, SEM, or light microscopy examinations. In these

cases, carbonyl absorption frequencies, known to accompany oxidized Prolene (see Figure 7), were not present, and thus *in vivo* oxidation did not occur.

Note the extensive fiber cracking and flaking; the product of crack propagation. Clearly the physical properties of Prolene have been severely compromised by UV light exposure (i.e. oxidative degradation).

Plaintiffs have posed the concept, without any scientific evidence, that our cleaning protocol (Figure 1) removes oxidation products formed and/or residing on Prolene's surface. However, purposeful oxidation of Prolene and subsequent cleaning proves unequivocally our process does not remove oxidized Prolene if it is present. When or if oxidized Prolene is present, as we have shown herein, it is evidenced by strong carbonyl absorption frequencies (Figure 8)[2]. The carbonyl group(s) responsible for the strong absorption are not removed by cleaning.

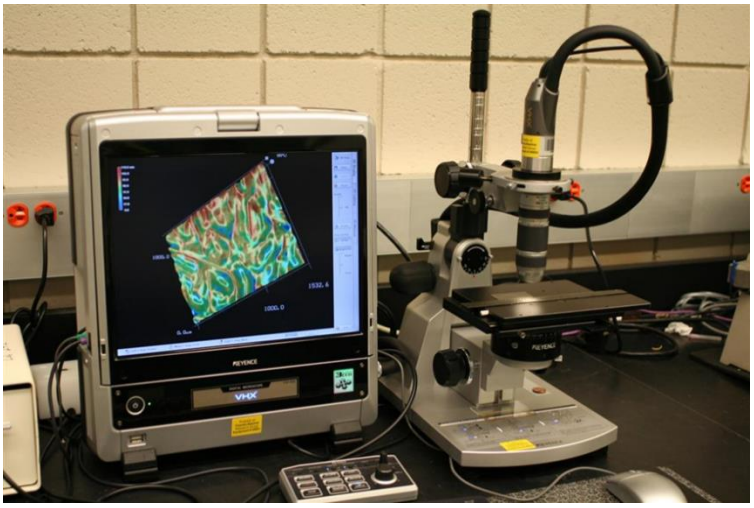

Figure 9. Keyence VHX-600 Digital Microscopy System

Figure 10. Zeiss Sigma VP FEG-SEM

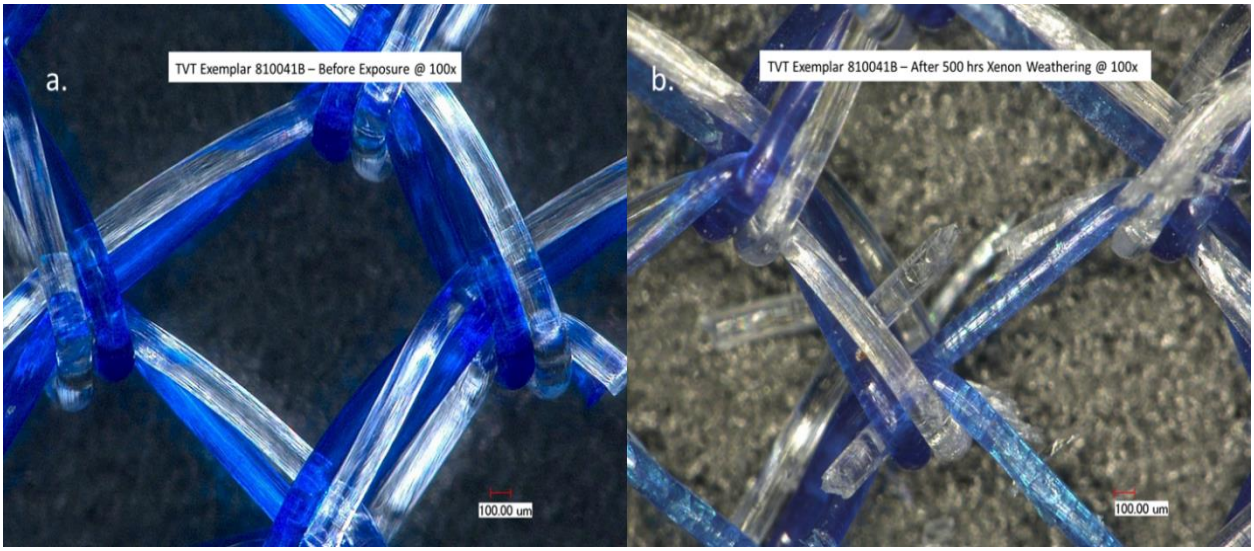

Figure 11. Light Microscopy of TVT 810041B Exemplar before UV exposure (a.) and after 500 hrs. UV exposure (b.)

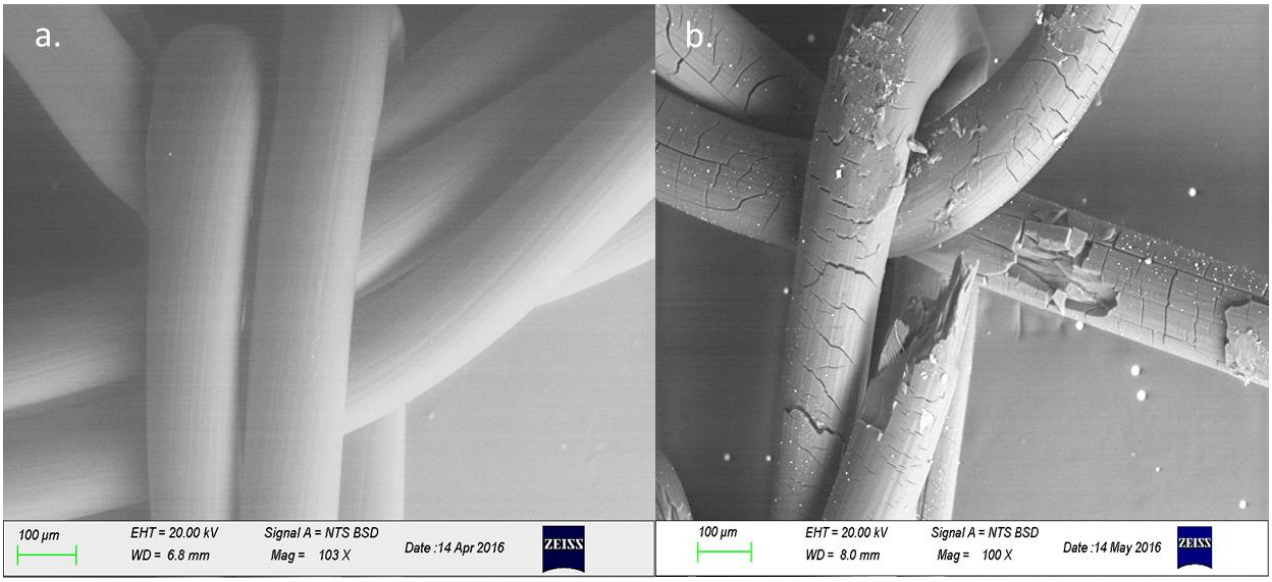

Figure 12. SEM of TVT 810041B Exemplar before UV exposure (a.) and after 500 hrs. UV exposure (b.)

At the time of my August 8, 2016 report, the oxidized Prolene exemplar had been processed through the After Cleaning 1 steps of Figure 1. Our experience has shown these first 6 steps to be those during which the majority of proteins are removed, and if Prolene oxidation is present these are the steps where oxidation would most likely be observed. Since submission of my prior report, FTIR characterization of the intentionally oxidized Prolene sample has been completed after each of the cleaning stages highlighted in Figure 1 i.e. After Cleaning 1, After Cleaning 2, After Cleaning 3,

After Cleaning 4, and After Cleaning 5. As previously noted herein, UV oxidation produces brittle Prolene. Thus, the ultrasonic (mechanical) steps of Figure 1 were omitted to prevent undue physical damage and complete disintegration of the Prolene fiber. Of note, the explant samples I have examined have held up very well during all Fig. 1 cleaning steps. The use of Proteinase K enzymatic reagent was unnecessary for use with the intentionally oxidized Prolene sample because it was an exemplar sample and therefore was never coated with proteins. Furthermore, any by-product of Proteinase K's enzymatic activity would have been water soluble, and Prolene is not water soluble. The purpose of Proteinase K in this protocol is to denature proteins, which were obviously absent from the exemplar sample.

The FTIR spectral overlay of Figure 13 confirms the carbonyl oxidation absorption of the intentionally oxidized Prolene sample has not diminished with progressive cleaning. This further proves the cleaning protocol does not deplete the carbonyl absorption of oxidized Prolene, should it be present in explanted samples.

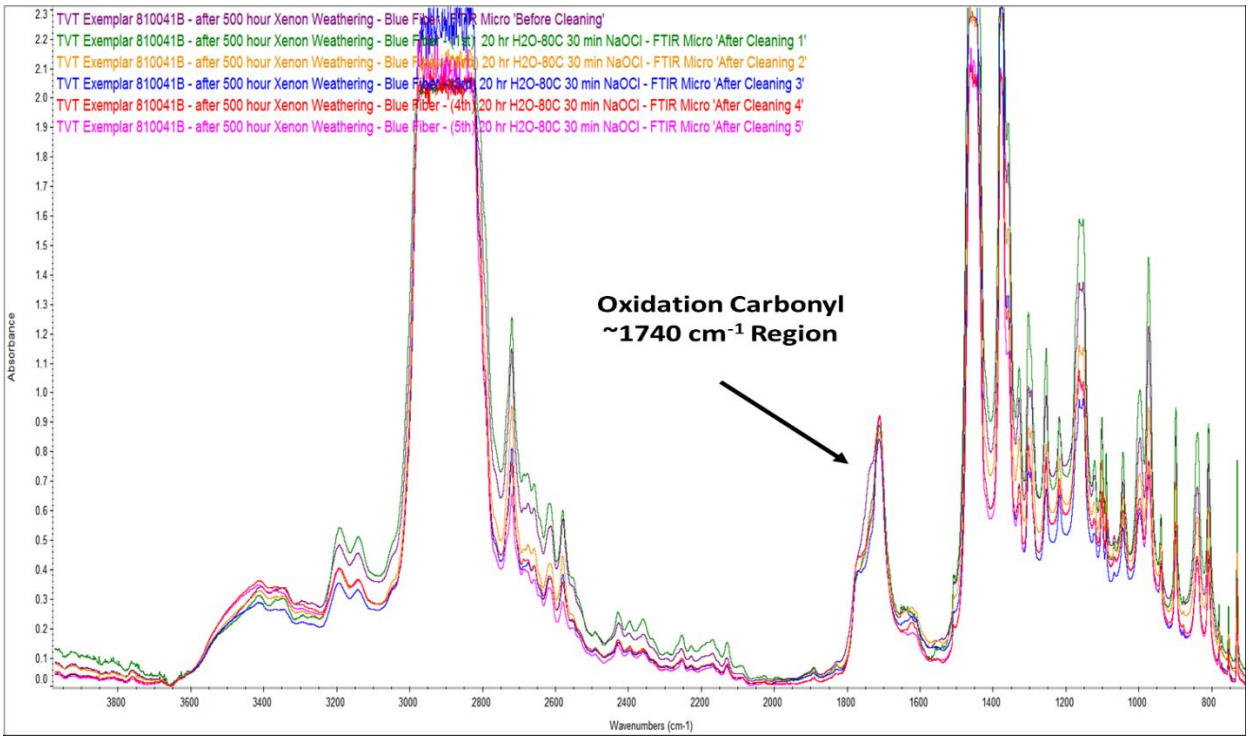

Figure 13. FTIR Spectral overlay of intentionally oxidized Prolene and the same sample after each of the cleaning steps highlighted in Figure 1.

I reserve the right to supplement this report and analysis, create additional exhibits as necessary to illustrate my testimony based upon the receipt of additional information, documents and materials, and to revise this report following the receipt of additional information and/or materials that have not yet been made available.

Shelby F. Thames, Ph.D.

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[1] ASTM G155 – Standard Practice for Operating Xenon Arc Light Apparatus for Exposure of Non-Metallic Materials

[2] Stuart, Barbara, H. (2004) Infrared Spectroscopy: Fundamentals and Applications, Analytical Techniques in the Sciences, ISBN: 9780470854280, Wiley